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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,218	09/08/2003	Ernst Peter Strecker	12013/56004	1060

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EXAMINER	
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ART UNIT	PAPER NUMBER
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,218	STRECKER, ERNST PETER	
	Examiner	Art Unit	
	David H. Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 17, 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-36,46,49,51-53,56 and 59-73* is/are pending in the application.

4a) Of the above claim(s) *60-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-36,46,49,51-53,56 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. An elongated hollow structure having an interior *annular* surface (instant claim 34, lines 1-2) is nowhere to be found in the original disclosure. The term "annular" means "of, relating to, or forming a ring", with a "ring" being "a circular band for holding, connecting, hanging, pulling, packing, or sealing", and a "band" being "a strip serving to join or hold things together" (*Merriam Webster's Collegiate Dictionary*, 10th edition: 1996). Elongated hollow structure surfaces having such a form are neither taught nor fairly suggested in the original disclosure.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 33-36, 46, 49, 51-53, 56, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhodes, US 5,122,154, in view of Schwartz, US 5,957,971. Rhodes discloses an elongated hollow structure having an interior annular surface defined at each of the "expandable, ring-like, stent members or sections **30**" (Rhodes: column 5, lines 63-64; Figures 1, 4, and 7) and a lining **28** more wrinkled or pleated in a compacted or initial state (*ibid.*: column 6, lines 5-14; Figures 3-6). Since the lining **28** may comprise expanded polytetrafluoroethylene (*ibid.*: column 5, lines 67-68) and Dacron mesh (*ibid.*: column 7, line 33), the lining inherently contains a plurality of through holes. The lining **28** may be positioned to contact the interior and exterior annular surfaces (*ibid.*: column 7, lines 1-3). Rhodes lacks mention of medications incorporated into the lining. However, such a feature was well known in the art at the time of the present invention (e.g., Schwartz: column 2, lines 24-27; column 4, line 30 et seq.; etc.), and to incorporate microencapsulated therapeutic substances (*ibid.*: column 4, lines 48-51) into the ePTFE, Dacron mesh, or other lining material of Rhodes would have been obvious to the ordinary practitioner in order to help prevent thrombosis, restenosis, inflammation, infection, and so on (*ibid.*: column 1, lines 46-55; column 4, lines 34-35 and 46-47; etc.), with further motivation (to combine such teachings) having been provided by the goal of Rhodes to preclude restenosis and the like (Rhodes: column 3, lines 47-52). Moreover, such a modification would have led to nothing more than predictable results to one of ordinary skill, because the drug delivery rate is controlled by the micro-capsules rather than porosity and other characteristics of the ePTFE, Dacron mesh, or other material selected for the lining (Schwartz: column 4, lines 49-

55). Regarding claim 35, the lining micro-capsules being biodegradable would have been an obvious means of facilitating drug delivery at a controlled rate; biodegradable linings were likewise well known in the art at the time of the present invention (*ibid.*: column 4, lines 27-29) and would have been an obvious variant in order to help eventually restore biological structure and reduce foreign material at the site (*ibid.*: column 6, lines 45-47). Regarding claim 49 and others, the layers containing different medications would have been obvious in order that the Dacron mesh layer contain a substance appropriate for treating the vessel wall (Rhodes: column 7, line 35) and the ePTFE sleeve incorporate a (different) substance or substances designed for the blood flow interface. Regarding claim 59, polyacrylics were common in the art and would have been an obvious alternative for the lining **28** because some acrylic resins are fibrous and elastomeric in nature.

Response to Applicant's Remarks

The word "elongated" has at least two meanings, including "stretched out" and "SLENDER" (*Merriam Webster's Collegiate Dictionary*, 10th edition: 1996). The Rhodes stent members **30** are certainly "stretched out" in the expanded state, as seen from a comparison of Figure 1 with Figure 3, and also meet the "SLENDER" definition in that a length (i.e., diameter or circumference) is greater than the width. Moreover, the Applicant's remarks do not explain how an "elongated" hollow structure can have an "annular" interior surface in the Applicant's own originally disclosed embodiments. The Applicant may *not* "carve out" a narrowed feature or limitation from a generalized statement like "variable lumen" (MPEP § 2163.05, sections II and III).

The Applicant argues that the Rhodes lining **28** does not have through holes. Gore, US 3,953,566, illustrates in Figure 1 that expanded polytetrafluoroethylene inherently (by virtue of the interconnected fibrils) has a plurality of tortuous through holes imparting "high porosity" to the material (e.g., abstract). Tissue ingrowth not extending into the interior of the graft (Rhodes: column 8, lines 57-59) does **not** imply that water molecules (or ions) and drug molecules (typically much smaller than tissue cells) are unable to pass through these through holes or pores. The Dacron mesh may be viewed as *part of* the Rhodes lining so as to define a composite; the Applicant's own lining may include two or more layers (instant claim 36).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/David H. Willse/
Primary Examiner
Art Unit 3738